

REMARKS

The preceding claim amendments and the following remarks are submitted as a full and complete response to the Office Action issued on March 24, 2009. Claims 1-20 have been cancelled without prejudice and claim 21 has been added. Claim 21 is directed to a process for producing a purified refolded monomeric MP52, wherein the monomeric MP52 contains an amino acid sequence as set forth in SEQ ID NO:1 in which Cystein at position 83 is replaced by Alanine. Support for the new claims can be found throughout the specification of the instant application, for example, Examples (6) – (9) at pages 14-18 and, as explained below in detail, in the original specification of Application Ser. No. 10/048,458 that led to U.S. Patent No. 6,972,321. Therefore, no new matter has been added. Upon entry of the claim amendments, claim 21 is pending.

Rejection under 35 U.S.C. §103(a)

The Patent Office has maintained the rejection of claims 1-8, 16-18, and 20 under 35 U.S.C. §103(a) as obvious over Andou, et al. (U.S. Patent No. 6,551,801) ("the '801 patent") in view of Hötten, et al. (U.S. Patent No. 6,972,321) ("the '321 patent"). Alleging that the Statement of Common Ownership accompanied with the response filed on December 4, 2008 is not sufficient, the Patent Office has concluded that the '801 and '321 patents cited in the previous rejection are not disqualified as prior art. Applicants remain convinced that Applicants have clearly and conspicuously established with the Statement of Common Ownership that the inventions claimed in claims 1-8, 16-18 and 20 of the present application and the two cited references, the

'801 and the '321 patents, were owned by the same person at the time the claimed invention was made.

Nonetheless, without acquiescing to the propriety of the Patent Office's position in this determination, Applicants have cancelled all the rejected claims and added new claim 21, the subject matter of which is sufficiently described in the original specification of the Application Serial No. 10/048,458 that led to the '321 patent ("the '458 application") as well as in the original specification of the present application. This claim amendment is made solely for the purpose of expediting prosecution of this application.

The instant application claims, among other priority claims, priority to the '458 application that led to the '321 patent. The '458 application is a national stage entry application of PCT/EP00/07600 filed on August 4, 2000. Therefore, Applicants respectfully submit that claim 21 is at least entitled to the effective filing date of August 4, 2000.

The '321 patent contains Examples that illustrate not only expression of monomeric MP52 in *E. coli*. but also solubilizing, direct refolding and purification of the expressed monomeric MP52. See cols. 11-12 of the '321 patent. More specifically, in the Examples, the mature part of human MP52 was mutated by converting Cystein to Alanine at position 465 of SEQ ID NO: 2. The plasmid pBP2 MP52ALA used in the Examples to express monomeric MP52 contained the nucleotide sequence coding for the amino acids 382-501 in SEQ ID No.2 with Alanine at position 465. The amino acids 382-501 in SEQ ID NO.: 2 are the same as those 1-119 of SEQ ID NO: 1 of the instant application in which amino acid at position 83 is Alanine. Thus, the monomeric MP52 expressed in the Examples of the '321 patent is the same monomeric MP52 containing

an amino acid sequence as set forth in SEQ ID NO: 1 with Alanine at position 83, which is recited in claim 21. The Examples of the '321 patent further state that the monomeric MP52 can be expressed in inclusion bodies which can be isolated according to standard procedures.

The Examples of the '321 patent also describe treating the inclusion bodies with a denaturing buffer to solubilize the monomeric MP52, which is then refolded in a refolding solution. See lines 30-36, col. 12 of the '321 patent. In the Examples of the '321 patent, the refolded monomeric MP52 was subjected to isoelectric purification and a further purification with reversed phase HPLC. See lines 38-41, col. 12 of the '321 patent. As such, each and every step of claim 21, which is tailored to a process for producing a purified refolded monomeric MP52 containing an amino acid sequence as set forth in SEQ ID NO: 1 with Alanine at position 83, is sufficiently described in the '321 patent.

Thus, Applicants respectfully submit that the specification of the '458 application that led to the '321 patent conveys with reasonable clarity to those skilled in the art that, as of the filing date of the '148 application, Applicants were in possession of the invention of claim 21. Accordingly, claim 21 is entitled to an effective filing date of August 4, 2000 and the '321 patent should be removed as prior art. EP 1 074 620 was not published until February 7, 2001 and thus, does not qualify as prior art against claim 21 of the instant application.

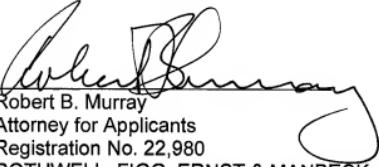
The '801 patent issued from the national stage filing of the application PCT/JP97/04784 which was published as WO 98/29559 on July 9, 1998. Thus, the Patent Office assumes that disclosure of the '801 patent would be identical to that of

WO98/20559. As admitted in the Office Action, however, WO98/20559 does not teach mutating Cysteine to prevent intermolecular disulfide bonds. As such, the '801 patent also lacks such teaching. Thus, the monomeric MP52 with Alanine at position 83 of SEQ ID NO:1, which results from replacing Cycteine at position 83 by Alanine, is not taught or suggested in either the '801 patent or WO98/20559.

To establish *prima facie* obviousness of a claimed invention, all the claim elements must be taught or suggested by the prior art. See In re Royka, 180 USPQ 580 (CCPA 1974). Since either the '801 patent or WO 98/20559 alone fails to teach all the elements of the claimed method, no *prima facie* case of obviousness has been established. Reconsideration and withdrawal of (1) the obviousness rejection based on the teachings of the '801 and the '321 patents and (2) the obviousness rejection based on the teachings of WO 98/29559 and EP 1 074 620 are respectfully requested.

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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